EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Brian Fairchild, on February 5, 2010.

The application has been amended as follows:

CANCEL all pending claims.

ENTER new claims 34-50:

34. (New) A pharmaceutical composition comprising desmopressin and a pharmaceutically acceptable carrier in a dosage form which dispenses by intranasal, transdermal, or intradermal administration from 0.5 ng up to 1 μg desmopressin.

35. (New) The pharmaceutical composition of claim 34 in a dosage form comprising a patch, gel, cream, ointment, or iontophore adapted for transdermal delivery.

36. (New) The pharmaceutical composition of claim 34 in a dosage form comprising a patch adapted for intradermal administration.

37. (New) The pharmaceutical composition of claim 34 in a dosage form comprising a spray adapted for intranasal delivery.

38. (New) The pharmaceutical composition of claim 34 in a dosage form sufficient to establish in a patient a steady plasma/serum desmopressin concentration of from about 0.1 picograms desmopressin per mL plasma/serum to 10 picograms desmopressin per mL plasma/serum.

39. (New) The pharmaceutical composition of claim 34 in a dosage form sufficient to establish~~es~~ in a patient a steady plasma/serum desmopressin concentration of from about 0.5 picograms desmopressin per mL plasma/serum to about 5.0 picograms desmopressin per mL plasma/serum.

40. (New) A pharmaceutical composition comprising desmopressin and a pharmaceutically acceptable carrier in a dosage form adapted for intranasal administration which dispenses from 0.1 ng up to 1 μg desmopressin and which when administered to a patient establishes a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per mL plasma/serum to about a maximum of 10.0 picograms desmopressin per mL plasma/serum and decreases urine production.

41. (New) The composition of claim 40 which establishes a steady plasma/serum desmopressin concentration of from about 0.5 picograms desmopressin per mL plasma/serum to about 5.0 picograms desmopressin per mL plasma/serum.

42. (New) A pharmaceutical composition comprising desmopressin and a pharmaceutically acceptable carrier in a dosage form adapted for intradermal or transdermal administration which dispenses from 0.1 ng up to 1 μg desmopressin and which when administered to a patient establishes a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per mL plasma/serum to about a maximum of 10.0 picograms desmopressin per mL plasma/serum and decreases urine production.

43. (New) The dosage form of claim 42 which establishes a steady plasma/serum desmopressin concentration of from about 0.5 picograms desmopressin per mL plasma/serum to about 5.0 picograms desmopressin per mL plasma/serum.

44. (New) The dosage form of claim 42 adapted for intradermal administration comprising a patch.

45. (New) The dosage form of claim 42 adapted for transdermal delivery and comprising a patch, gel, cream, ointment, or iontophore.

46. (New) The composition of claim 34 which establishes said plasma/serum desmopressin concentration range for a time between four and six hours.

47. (New) The composition of claim 40 which establishes said plasma/serum desmopressin concentration range for a time between four and six hours.

48. (New) The composition of claim 41 which establishes said plasma/serum desmopressin concentration range for a time between four and six hours.

49. (New) The composition of claim 42 which establishes said plasma/serum desmopressin concentration range for a time between four and six hours.

50. (New) The composition of claim 43 which establishes said plasma/serum desmopressin concentration range for a time between four and six hours.

The following is an examiner's statement of reasons for allowance: The claims have been amended such that the desmopressin found in the dosage is below that which was previously understood to be therapeutically effective for a child/infant. The lowest dose for a child/infant is above 1 μg, and the artisan understood this to be the lowest effective dosage and would not have considered making a lower dose pharmaceutical for a child/infant. Furthermore, the amendments to the desmopressin ranges find inherent support in the specification (throughout) and are consistent with MPEP 2163.05 (III).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654